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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,621	12/21/2001	Walter Callen	DIVER1350-6	9848
45975	7590	11/26/2004	EXAMINER	
DIVERSA C/O MOFO S.D. 3811 VALLEY CENTER DRIVE, SUITE 500 SAN DIEGO, CA 92130			HUTSON, RICHARD G	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/034,621

Applicant(s)

CALLEN ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-12, 16, 17, 28-33, 36, 37 and 39 to 55 is/are pending in the application.
- 4a) Of the above claim(s) 34, 35, 38 and 44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-12, 17, 28-33, 36, 37, 39-43 and 45-55 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/25/2004 has been entered.

Applicants amendment of claims 1, 4, 5, 7-10, 12, 16, 17 and 35, cancellation of claim 8 and 13-15 and the addition of new claims 45-55 in the papers of 8/25/2004 and 9/20/2004, is acknowledged. Claims 1-7, 9-12, 16, 17, 28-33, 36, 37 and 39 to 55 are still at issue and are present for examination.

Applicants' arguments filed on 8/25/2004 and 9/20/2004, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 34, 35, 38 and 44 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Objections

Claims 9, 10, 12, 16, 17, 45 and 46-50 are objected to because of the following informalities:

Newly amended claims 9, 10, 12, 16, 17, 45, 46-50 are grammatically awkward in the way it is structured/written. It is suggested that the claim be amended (i.e. perhaps using punctuation) so that the claim reads clearer.

It is suggested that applicants amend claim 16 to recite "enzymatically active fragments thereof..." in order to specify that the enzymatically active fragments referred to are from SEQ ID NO: 2.

. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly added claims 50-54 are indefinite in there reference to the "active site of the polymerase". This is especially evident since applicants are using the reference to the "active site of the polymerase" as a means of structurally describing the claimed nucleic acids. It is unclear what applicants intend to be considered the "active site of

the polymerase" as this phrase would be unclear to one of ordinary skill in the art, and thus the claims with this reference are unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 and 50-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to previous claims 4-6, 12-17 and 39-43. In response to this previous rejection, applicants have amended claims 1, 4, 5, 7-10, 12, 16, 17 and 35, cancellation of claim 8 and 13-15 and the addition of new claims 45-55. Claims 4-6, 12-17 and 39-43 have been withdrawn from the rejection based on applicants amendment of the claims in the paper of 8/25/2004.

Claim 17 remains rejected under this statute, in spite of applicants previous amendment. Applicants only traversal with respect to claim 17 is that amended claim 17 is directed to nucleic acids encoding a polymerase and comprising at least 30 consecutive amino acids of a polypeptide having a sequence set forth in SEQ ID NO: 2 or enzymatically active fragments having polymerase activity. This being the only

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traversal regarding the rejection of newly amended claim 17 under written description, applicants traversal is not found persuasive for the reasons previously stated.

Applicants structural limitation is not sufficient enough such that applicants have adequately described the claimed genus's structure to function relationship.

Claims 50-54 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the reference in newly added claims 50-54, (See also above 112 second paragraph rejection) which recites "active site of the polymerase" and its use as a means of structurally describing the claimed polymerases is not supported by the specification at the time of filing. It is requested that applicants indicate where in the specification applicants have support for such a description of the claimed polymerases.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-7, 9-12, 17, 28-33, 36, 37, 39-43 and 45-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acid comprising SEQ ID NO: 1 and encoding a polypeptide having polymerase activity, does not reasonably provide enablement for any nucleic acid comprising a mere 85%

identity to SEQ ID NO: 1 and encoding a polypeptide having polymerase activity, or any nucleic acid encoding a mere 30 consecutive amino acids of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 1-3, 4-6, 7-11, 12-17, 28-33, 36 and 37. In response to this previous rejection, applicants have amended claims 4, 12, 16, and 17 and claims 13-15 and the added new claims 45-55. Applicants traverse the rejection of the newly amended claims in the papers of 8/25/2004 and 9/20/2004.

Applicants continued traversal as presented in the papers of 8/25/2004 and 9/20/2004, has been fully considered.

Applicants continue to submit that the specification enabled the skilled artisan at the time of the invention to identify and make and use, a genus of polymerases to practice the claimed invention. Applicants point out, as declared by Dr. Jay Short, one of the inventors of the invention, that the state of the art and the level of the person of ordinary skill in the art was very high and that one of skilled in the art could have used routine methods known in the art at the time of the invention, including those described in the specification, to screen for nucleic acids encoding polypeptides having a certain percent sequence identity to SEQ ID NO: 1 for various polymerase activities.

Applicants continued argument and the declaration submitted by Dr. Short have been fully considered, however are found nonpersuasive for the following. First as

discussed below under the 102 rejection, applicants claims are not necessarily limited to those nucleic acids encoding polymerases in which the complete nucleic acid has a specified structural relationship to either SEQ ID NO: 1 or SEQ ID NO: 2, but rather many of applicants claims are drawn to those nucleic acids which "comprise a sequence" which has a structural relationship with SEQ ID NO: 1 or SEQ ID NO: 2.

In response to applicants arguments that applicants have provided the skilled artisan with a reasonable amount of guidance with respect to how to make changes in a specified nucleic acid and how to screen for polymerases, applicants are again reminded that while the necessity to screen for some unspecified embodiments are allowed, the necessity for excessive screening without sufficient guidance clearly constitutes undue experimentation.

Applicants are again reminded that the currently claimed genus is not drawn to those nucleic acids which are themselves defined as the complete nucleic acid structurally relates to SEQ ID NO: 1 or SEQ ID NO: 2, but to those nucleic acids which "comprise a sequence" which is structurally defined relative to SEQ ID NO: 1 and SEQ ID NO: 2 and that such a broadly defined genus necessitates more guidance than is available to the skilled artisan in the art and applicants specification.

As previously stated, without such guidance one of ordinary skill would be reduced to the necessity of producing and testing all of the virtually infinite possibilities. This would clearly constitute undue experimentation. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect

to the direction in which the experimentation should proceed. While some guidance as argued by applicants' representative has been provided in the instant specification, such guidance is insufficient to enable those currently claimed nucleic acids which "comprise a sequence" with the defined structural relationship to SEQ ID NOs: 1 and 2.

Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions would be acceptable to retain the desired activity/function and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it would require undue experimentation for one skilled in the art to arrive at the majority of those polypeptides of the claimed genus defined merely as all nucleic acids "comprising a sequence" having at least 85% sequence identity to SEQ ID NO: 1 and encoding a polypeptide having polymerase activity.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including those nucleic acids comprising a sequence with the defined structural relationship to SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 4-6, 7, 11, 28, 29-33, 36, 37, 39-43, 45 and 51-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Gelfand et al. (U.S. Patent No. 5,491,086, issued 2/13/1996).

The rejection was stated in the previous office action as it applied to previous claims 4-6, 7-11, 12-15, 17 and 39-43. In response to this previous rejection, applicants have amended claims 4, 12, 16, and 17 and cancelled claims 13-15 and the added new claims 45-55. Applicants traverse the rejection of the newly amended claims in the paper of 8/25/2004.

Applicants traverse the previous rejection (referencing claims 4-6) on the basis that applicants have amended the claim to include the stringent hybridization wash conditions limitation and the claimed nucleic acids will not hybridize to the nucleic acid taught by Gelfand, which is 66.5% identical to the instantly disclosed SEQ ID NO: 1. Applicants further traverse the rejection (referencing claims 7-11) on the basis that the instant amendments address any concern of whether Gelfand teaches nucleic acids which read on the rejected claims, as these are drawn to nucleic acids which have at least 70 to 95% sequence identity to SEQ ID NO: 1.

Applicants complete traversal of the above rejection is acknowledged, however, found non-persuasive on the basis that the currently rejected claims are not drawn to sequences which are at least 70%-90% identical to SEQ ID NO: 1, but rather they continue to be drawn to sequences which comprise a sequence which is at least 70%-90% identical or hybridizes to a sequence of SEQ ID NO: 1. Similarly, the claimed nucleic acids need not themselves hybridize to a sequence set forth in SEQ ID NO: 1, but merely "comprise a sequence" that will hybridize under the specified conditions to SEQ ID NO: 1, which the nucleic acids taught by Gelfand et al. do. It is noted to applicants that this line of reasoning was stated previously in this rejection.

It is noted that in addition to claims 4-6, 7, 11, 28, 29-33, 36, 37, 39-43, for which the previous rejection is maintained, claims 1-3, 45 and 51-55 are included in the rejection because as discussed above these claims each recite "An isolated or recombinant nucleic acid comprising a sequence having ..." The reference to "a sequence" is interpreted as if there exist multiple sequences, and applicants are specifying a, as in a single. Given this reasonable interpretation, it could be said that SEQ ID NO: 1 comprises many different, contiguous and overlapping sequences. Applicants rejected claims merely specifies that the claimed nucleic acid comprises "a sequence" as in a single sequence, as opposed to "the sequence of SEQ ID NO: 1.

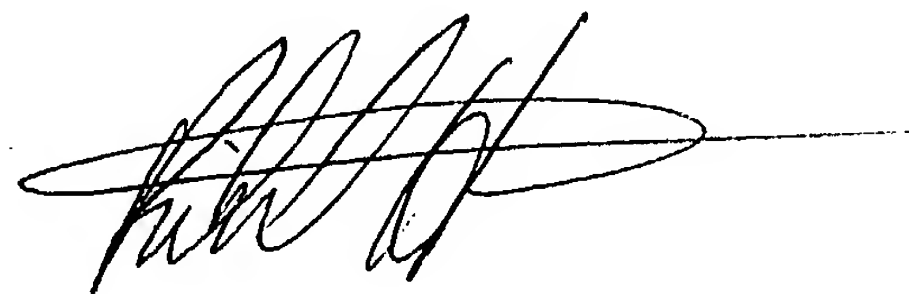
Thus, claims 1-3, 4-6, 7, 11, 28, 29-33, 36, 37, 39-43, 45 and 51-55 stand rejected as anticipated by Gelfand et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Huston whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'R. G. Huston', with a long horizontal line extending to the right.

Richard G Huston, Ph.D.
Primary Examiner
Art Unit 1652

rg
11/16/2004